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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte DONALD E. BOBO, JR.

Appeal 2009-000892
Application 10/021,132
Technology Center 3700

Decided: August 13, 2009

Before DEMETRA J. MILLS, ERIC GRIMES, and MELANIE L. McCOLLUM, *Administrative Patent Judges*.

McCOLLUM, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a medicament delivery method. The Examiner has rejected the claims as not being supported by an adequate written description, as anticipated, and/or as obvious. We have jurisdiction under 35 U.S.C. § 6(b). We affirm-in-part.

STATEMENT OF THE CASE

Claims 36-44 are pending and on appeal (App. Br. 3). We will focus on claims 36, 39, 41, and 42, which read as follows:

36. A method of delivering medicament to tissue in a chamber of the heart while traversing a right atrium and sealably traversing an atrial septum, comprising:

introducing a medicament delivery catheter though an endoluminal entry point and advancing the catheter through a circulatory system;

directing the catheter to traverse the right atrium and puncture the atrial septum of a patient to form an opening;

supportively engaging the atrial septum at the opening with the medicament delivery catheter;

sealing the opening with the medicament delivery catheter;

further advancing the medicament delivery catheter through the sealed opening to a surface on the chamber of the heart; and

creating a channel through the surface of the heart chamber and delivering medicament into the channel.

39. A method of delivering medicament to tissue while preventing medicament washout, comprising:

providing a medicament delivery catheter having a tissue engaging surface with at least one vacuum operated tissue stabilizer port;

providing access to a tissue surface;

advancing the catheter to the tissue surface;

positioning the tissue engaging surface proximate the tissue surface;

sealably engaging the tissue engaging surface to the tissue surface by activating a vacuum force through the tissue stabilizer port;

forming a sealed opening in the tissue surface;

delivering medicament through the sealed opening in the tissue surface; and

preventing the medicament from passing between the tissue engaging surface and the tissue surface to a location outside the sealed opening.

41. The method of claim [39 wherein the catheter comprises at least one vacuum port positioned radially about the tissue engaging surface and at least one vacuum lumen located within the catheter and] wherein the

catheter comprises four vacuum ports positioned on the tissue engaging surface.

42. A method of delivering medicament to tissue while preventing medicament washout, comprising:

providing a medicament delivery catheter having a tissue engaging surface with a sealing balloon;

providing access to a tissue surface;

advancing the catheter to the tissue surface;

positioning the tissue engaging surface proximate the tissue surface;

sealably engaging the tissue engaging surface to the tissue surface by inflating the sealing balloon;

forming a sealed opening in the tissue surface;

delivering medicament through the sealed opening in the tissue surface; and,

preventing the medicament from passing between the tissue engaging surface and the tissue surface to a location outside of the sealed opening.

Claims 36-38 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement (Ans. 3).

Claims 42-44 stand rejected under 35 U.S.C. § 102(e) as anticipated by Flaherty (US 6,283,951 B1, Sep. 4, 2001) (Ans. 3).

Claims 36-38 stand rejected under 35 U.S.C. § 103(a) as obvious over Flaherty in view of Jenkins (US 6,645,199 B1, Nov. 11, 2003), Cox (US 6,161,543, Dec. 19, 2000), and Kalloo (US 2001/0049497 A1, Dec. 6, 2001) (Ans. 3).

Claims 39 and 40 stand rejected under 35 U.S.C. § 103(a) as obvious over Flaherty in view of Jenkins and Mueller (US 5,725,523, Mar. 10, 1998) (Ans. 4).

Claim 41 stands rejected under 35 U.S.C. § 103(a) as obvious over Flaherty in view of Jenkins, Mueller, and Jeevanandam (US 5,807,388, Sep. 15, 1998) (Ans. 4).

WRITTEN DESCRIPTION

The Examiner finds that claim 36 "contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention" (Ans. 3). In particular, the Examiner finds that the "originally filed disclosure . . . is silent on 'supportively engaging the atrial septum with the medicament delivery catheter ...'" (*id.*). The Examiner also finds:

> [I]f the term "medicament delivery catheter" is construed to be the "device 300' " set forth in the disclosure, this would require that after the device 300' is "supportively engaging" and thus attached to the atrial septum via the balloons thereon, it is then further advanced, which would cause tearing and destruction of the atrial septum, which is still attached, by virtue of the device 300' "supportively engaging" it, as the device 300' is being advanced. Thus as this would have a catastrophic effect on the health of the patient, the originally filed disclosure, drawn to medically treating the beating heart, rather than destroying it, possibly beyond repair, is not a concept that can fairly be read thereinto.

(*Id.* at 5.)

Appellant argues that "[s]upport for this recited language can be found in paragraph 015[2][1] of the present Application (page 38, line 19-page 39, line 2; amended March 30, 2006)" (App. Br. 9).

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[1] Appellant referred to paragraph 0151 of the published patent application (*see* App. Br. 3, footnote 1), which corresponds to paragraph 0152 of the original application, which was amended in March 2006. We refer herein to the paragraph numbering of the application as filed.

Issue

Did the Examiner err in finding that the Specification does not support the recitation in claim 36 of "supportively engaging the atrial septum with the medicament delivery catheter ..."?

Findings of Fact

1. The Specification discloses that an "embodiment of the present invention is illustrated in Fig. 42a-42c" (Spec. ¶ [0152]). Figs. 42a-42c are directed to "a tissue-removal and medicament-delivery device" (*id.* at ¶¶ [0073]-[0075]).

2. The Specification discloses that, "[a]s shown in Fig. 42a, the device 300' comprises a deflated first balloon 316a and a deflated second balloon 316b in communication with at least one internal inflation lumen 318" (*id.* at ¶ [0152]).

3. The Specification also discloses:

> The device 300' is advanced to a position proximate the area of interest and a hole 320 is formed in the tissue 308a. As shown in Fig. 42b, the distal portion of the device 300' and the deflated second balloon 316b is advanced therethrough. Thereafter, the first balloon 316a and the second balloon 316b are inflated, thereby supportively engaging the tissue 308a disposed therebetween. Thereafter the device 300' is advanced to and engages tissue 308b.

(*Id.*)

4. In addition, the Specification discloses that this "embodiment may be used to isolate discrete portion of tissue or organs. For example, the present invention may be utilized to sealably traverse the atrial septum and precisely ablate and inject medicament to an isolated chamber of the heart." (*Id.* (as originally filed).)

Principles of Law

"To fulfill the written description requirement, the patent specification 'must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed.'" *Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479 (Fed. Cir. 1998). "[T]he PTO has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims." *In re Wertheim*, 541 F.2d 257, 263 (CCPA 1976).

Analysis

The Specification discloses a medicament-delivery device 300' having first and second balloons (Findings of Fact (FF) 1-2). The Specification also discloses that the distal portion of device 300' (including the deflated second balloon 316b) is advanced through a hole 320 formed in tissue 308a and that, thereafter, "the first balloon 316a and the second balloon 316b are inflated, thereby supportively engaging the tissue 308a disposed therebetween" (FF 3). In addition, the Specification discloses that this device "may be utilized to sealably traverse the atrial septum" (FF 4). Thus, we agree with Appellant that the Specification provides support for the recitation "supportively engaging the atrial septum at the opening with the medicament delivery catheter."

The Specification additionally states that "[t]hereafter the device 300' is advanced to and engages tissue 308b" (FF 3). Thus, we agree with Appellant that the Specification additionally supports supportively engaging the atrial septum as the medicament-delivery catheter is being advanced.

Conclusion

The Examiner erred in finding that the Specification does not support the recitation in claim 36 of "supportively engaging the atrial septum with the medicament delivery catheter ..." We therefore reverse the written description rejection of claims 36-38.

ANTICIPATION

The Examiner finds that Flaherty teaches the method of claim 42 (Ans. 3). The Examiner refers to Flaherty "Figure 6 and column 13, line 19 to column 14, line 26" (Jun. 30, 2006, Rejection 2). The Examiner finds that Flaherty discusses "the problem of wash-out, and the attendant global side effects that arise from administering more of the treating material to remedy the problem of wash-out . . . , and the desire to remedy these problems" (Ans. 6-7). Therefore, the Examiner finds that "the porous balloon in the embodiment of Figure 6 must be construed to provide a degree of 'sealing' which at least partially overlaps the spectrum of meaning encompassed by the term 'sealing' as used in the claims at bar" (*id.* at 7). The Examiner also finds that "Flaherty teaches the possession of the concept of non-porous balloons" (*id.* at 6).

Appellant argues that Flaherty does not disclose "sealably engaging the tissue engaging surface to the tissue surface by inflating the sealing balloon," as recited in claim 42 (App. Br. 13).

Issue

Did the Examiner err in finding that Flaherty anticipates claim 42?

Findings of Fact

5. Flaherty relates "to systems and methods for delivering substances into a body, more particularly to systems and methods that use the cardiovascular system as a conduit to deliver drugs . . . directly to selected tissue regions within the body" (Flaherty, col. 1, ll. 11-16).

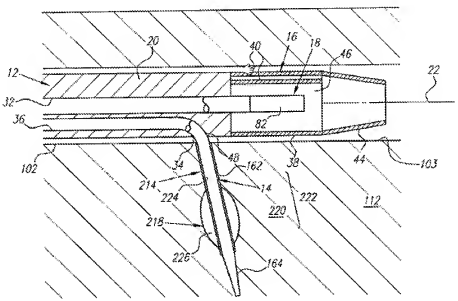
6. Flaherty discloses that, "[i]n current medical therapy, one method of delivering such drugs involves percutaneously introducing an infusion catheter into the patient's cardiovascular system" (*id.* at col. 1, ll. 40-42).

7. Flaherty also discloses that the "infusion catheter often includes a porous perfusion balloon on its distal end," pores in the balloon being "arranged to direct the drug from the balloon towards the arterial wall to improve penetration into the arterial wall and attempt to localize delivery" (*id.* at col. 1, ll. 58-63).

8. In addition, Flaherty discloses that, as "an alternative to perfusion balloons and/or infusion catheters, a drug may be embedded in or deposited on a catheter, e.g. in the catheter wall, the wall of a non-porous balloon on the catheter, and/or a coating on the catheter" (*id.* at col. 2, ll. 11-14).

9. In discussing its invention, Flaherty discloses a transvascular catheter system including a puncturing element that "includes a distal tip adapted to penetrate a wall of a blood vessel to access a tissue region beyond the wall of the blood vessel" (*id.* at col. 3, l. 58, to col. 4, l. 1).

10. Flaherty Figure 6 is reproduced below:



Flaherty Figure 6 depicts a transvascular catheter system including "a drug delivery catheter deployed into a remote tissue region" (*id.* at col. 8, ll. 21-25). Flaherty discloses deploying drug delivery catheter 214 over puncturing element 14, which includes a solid needle or guide wire assembly 162 (*id.* at col. 13, ll. 29-34). Flaherty also discloses that the drug delivery catheter 214 includes "a porous balloon 218 for infusing the drug in a predetermined pattern within the tissue region 220" (*id.* at col. 13, ll. 39-41).

11. To use the device of Figure 6, Flaherty discloses introducing the catheter 12 percutaneously into a blood vessel 102, deploying the guide wire assembly 162 transvascularly to access the selected tissue region 220, advancing the drug delivery catheter 214 over the guide wire assembly 162, and inflating the balloon 218, "expanding it from a collapsed condition

around the drug delivery catheter 214 to an enlarged condition contacting the surrounding tissue 220" (*id.* at col. 13, ll. 53-63).

Principles of Law

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros., Inc. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987).

Analysis

Flaherty discloses deploying the guide wire assembly 162 transvascularly to access the selected tissue region 220 and advancing the drug delivery catheter 214 over the guide wire assembly 162 (FF 11). Thus, Flaherty discloses forming an opening in a tissue surface. In particular, when the guide wire assembly 162 punctures the blood vessel and continues into the tissue, an opening in a tissue surface is formed.

In addition, Flaherty discloses inflating a balloon (FF 11). Given that this balloon is porous (FF 10), we agree with Appellant that inflating this balloon would not sealably engage a tissue engaging surface of the catheter to a tissue surface. However, even if we assume that it does, the Examiner has not adequately explained how inflating the balloon sealably engages the tissue engaging surface to the tissue surface into which an opening is formed. Thus, the Examiner has not adequately explained how Flaherty discloses a method comprising both "sealably engaging the tissue engaging surface to the tissue surface by inflating the sealing balloon" and "forming a sealed opening in the tissue surface," as recited in claim 42.

The Examiner also notes that Flaherty teaches a non-porous balloon (Ans. 6; *see* FF 8). However, the Examiner has not set forth a prima facie case that Flaherty discloses using a non-porous balloon in the method of claim 42.

Conclusion

The Examiner erred in finding that Flaherty anticipates claim 42. We therefore reverse the anticipation rejection of claim 42 and of claims 43 and 44, which depend from claim 42.

OBVIOUSNESS I

The Examiner rejects claims 36-38 as obvious over Flaherty in view of Jenkins, Cox, and Kalloo (Ans. 3). The Examiner relies on Flaherty for teaching "a method of myocardial drug delivery" (*id.* at 3-4). The Examiner relies on Jenkins for teaching "a method of crossing the septum as claimed" (*id.* at 4). The Examiner relies on Cox for teaching "the use of means to seal the tissue around an internal chamber ablation device to prevent bleeding when working on a beating heart" (*id.*). The Examiner relies on Kalloo for teaching "the use of a dual balloon stabilizing means to aid in the placement of a surgical device" (*id.*). The Examiner concludes that it would have been obvious,

> in order to access the myocardium transvenously, to employ the method of Jenkins et al, since Flaherty et al teach no details of the transvenous placement method; and . . . to employ the balloons of Kalloo et al, since this would both stabilize the devices as well as seal the opening, which is desirable, since this prevents bleeding when the procedure is performed on a beating heart, as taught by Cox.

(*Id.*)

Appellant argues that none of Flaherty, Cox, and Jenkins teaches "supportively engaging the atrial septum at an opening with the medicament delivery catheter and sealing the opening with the medicament delivery catheter" (App. Br. 15-17). Appellant also argues that "simply combining the balloons of *The Kalloo et al. Publication* will not achieve the invention as recited in claim 36" (App. Br. 16). In particular, Appellant argues:

> While the device of *The Kalloo et al. Publication* may include balloons, these balloons are not appropriate for use with the present invention as claimed. For example, the *Kalloo* balloons are sized and configured for use on an endoscope during entry into a stomach and therefore include a relatively large diameter, large thickness and greater distance between both balloons. Simply placing these *Kalloo* balloons on a device appropriately sized for a cardiac procedure as the Examiner suggests will not result in a device that can engage and seal an atrial septum as claimed in claim 36 without some additional teaching as to how such an adaptation may be performed. The atrial septum is small and relatively delicate, requiring different design considerations than the larger and more rugged entry into the stomach.

(*Id.*)

Issue

Did the Examiner err in concluding that it would have been obvious to include Kalloo's balloons in a catheter that traverses the atrial septum in order to seal the opening therein?

Findings of Fact

12. Flaherty discloses "a transvascular catheter system 10 for delivering a drug to a remote tissue region 220 within the myocardium" (Flaherty, col. 13, ll. 19-22).

13. Jenkins discloses an "apparatus that facilitates the creation of circumferential lesions in body tissue," the apparatus including "a first probe having a loop structure . . . and a second probe with an expandable push structure" (Jenkins, Abstract).

14. Jenkins also discloses:

> A transseptal technique may be used to direct two separate probes through two separate sheaths . . . from the right atria, through the fossa ovalis and into the left atria. One puncture may be made for each of the probes. Alternatively, given the elasticity of the membranous portion of the atrial septum, a single puncture may be made. Once one of the probes has been inserted through the puncture, the other probe can be wedged into the left atria between the inserted probe and the perimeter of the puncture.

(*Id.* at col. 6, ll. 42-51.)

15. Cox discloses "surgical systems and methods for ablating heart tissue" (Cox, Abstract).

16. When the procedure is conducted while the heart is still beating, Cox discloses that "it is necessary to form a hemostatic seal between the ablation device and the penetration" (*id.* at col. 15, ll. 56-59).

17. Kalloo discloses "a technique for accessing the peritoneal cavity via the wall of the digestive tract . . . so that examination of and/or a surgical procedure in the peritoneal cavity can be conducted via the wall of the digestive tract with the use of a flexible endoscope" (Kalloo, Abstract).

18. In particular, Kalloo discloses a device including an "overtube 10 having a conduit 12 that is sized to receive an endoscope therethrough" (*id.* at ¶ [0028]).

19. Kalloo also discloses that the "distal end 20 of the overtube is adapted to be anchored to the wall of, e.g., the stomach. . . . Such an anchoring and sealing function is provided . . . by providing a pair of anchoring cuffs or balloons 22, 24 adjacent the distal end of the overtube." (*Id.* at ¶ [0031].)

20. In addition, Kalloo discloses:

> [T]he distal end of the overtube is inserted through an incision formed in the gastric wall and the anchoring balloons provided adjacent the distal end are inflated, with one inside the peritoneal cavity and the other one inside the stomach. . . . The inflated balloons anchor the distal end 20 of the overtube 10 to the gastric wall to prevent the overtube from migrating further into the peritoneal cavity or back into the stomach and isolate the peritoneal cavity from the gastric cavity.

(*Id.* at ¶ [0032].)

Principles of Law

"The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *KSR Int'l v. Teleflex Inc.*, 550 U.S. 398, 416 (2007). Obviousness analysis "need not seek out precise teachings directed to specific subject matter of the challenged claim." *Id.* at 418. Instead, it proper to "take account of the inferences and creative steps that a person of ordinary skill in the art would employ." *Id.* "A person of ordinary skill is also a person of ordinary creativity, not an automaton." *Id.* at 421.

Analysis

Kalloo discloses including two balloons on the overtube of an endoscope device and positioning each balloon on one side of the stomach wall to anchor and seal the stomach wall (FF 17-20). We agree with the

Examiner that it would have been prima facie obvious to include balloons in a device that punctures the atrial septum in order to anchor the device and seal the atrial septum (Ans. 4). In particular, we agree with the Examiner that one of ordinary skill in the art would have been able select appropriately sized and configured balloons to seal an atrial septum (*id.* at 9).

Conclusion

Appellant has not shown that the Examiner erred in concluding that it would have been obvious to include Kalloo's balloons in a catheter that traverses the atrial septum in order to seal the opening therein. We therefore affirm the obviousness rejection of claim 36. Claims 37 and 38 have not been argued separately and therefore fall with claim 36. 37 C.F.R. § 41.37(c)(1)(vii).

OBVIOUSNESS II

The Examiner rejects claims 39 and 40 as obvious over Flaherty in view of Jenkins and Mueller (Ans. 4). The Examiner relies on Flaherty and Jenkins as discussed above (*id.*). The Examiner relies on Mueller for teaching "sealing to the cardiac tissue using a vacuum port before creating a channel in the tissue" (*id.*). The Examiner concludes that it would have been obvious "to employ the combined drug injection . . . method of Flaherty et al and Jenkins et al in the method of Mueller . . . since this is desirable to help maintain the channels, as taught by Flaherty et al, thus producing a method such as claimed" (*id.*).

Appellant argues:

> *The Mueller Patent* is directed to a device which creates a seal against an area of tissue by providing suction or a vacuum. This suction, when combined with *The Flaherty et al. Patent*

> would likely cause the medicament within the porous balloon to be drawn out and sucked up by the vacuum, reducing the pressure in the porous balloon and preventing the creation of a seal. Thus, medicament may pass between the balloon and the tissue surface.

(App. Br. 18.)

Issue

Did the Examiner err in concluding that the applied references render claim 39 obvious?

Findings of Fact

21. Flaherty discloses that its "guide wire assembly 162 may include an anchoring tip (not shown) for fixing the distal tip 164 of the guide wire assembly 162 in the tissue region 220" (Flaherty, col. 13, ll. 33-36).

22. Mueller discloses a "balloon end contact scope device for performing laser-assisted transmyocardial revascularization (TMR) or other surgical and catheter procedures," the device including "an internal guide tube extending through the balloon portion for directing a laser delivery means or other surgical or catheter device through the visualization balloon toward the area being visualized" (Mueller, Abstract).

23. TMR is "the creation of channels from the epicardial to the endocardial portions of the heart. The procedure using needles in a form of 'myocardial acupuncture'" is known. (*Id.* at col. 2, l. 64, to col. 3, l. 5.)

24. Mueller also discloses:

> A fluoroscope locator and guide tether device for use as a fluoroscopic marker or locator as w[e]ll as a guide tether for a monorail or other mounted-type fluoroscopic marking tools and materials, laser delivery means, visualization mean[s] and other

> surgical equipment which can be positioned precisely along the guide tether adjacent tissue to be inspected or treated.

(*Id.* at col. 6, ll. 59-65.)

25. In addition, Mueller discloses that the fluoroscope locator and guide tether device includes a securing means, which is preferably a suction cup, "for securing the proximal end of the guide tether portion of the device to tissue or other structure adjacent the subject tissue being visualized, marked or otherwise treated" (*id.* at col. 7, ll. 5-9).

26. Mueller also discloses a "vacuum source connected to the securing means, thereby maintaining the securing means attached to tissue or other structure by a vacuum seal" (*id.* at col. 7, ll. 23-28).

Principles of Law

"In rejecting claims under 35 U.S.C. § 103, the examiner bears the initial burden of presenting a *prima facie* case of obviousness. Only if that burden is met, does the burden of coming forward with evidence or argument shift to the applicant." *In re Rijckaert*, 9 F.3d 1531, 1532 (Fed. Cir. 1993) (citation omitted).

A claim "composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." *KSR Int'l v. Teleflex Inc.*, 550 U.S. 398, 418 (2007). The relevant question is "whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue." *Id.*

Analysis

Mueller discloses a fluoroscope locator and guide tether device including a securing means, which is preferably a suction cup, connected to a vacuum source "for securing the proximal end of the guide tether portion

of the device to tissue or other structure adjacent the subject tissue being visualized, marked or otherwise treated" (FF 25-26). However, the Examiner has not adequately explained how or why this disclosure is being combined with Flaherty and Jenkins to result in the method of claim 39.

The Examiner argues that it would have been obvious "to employ the combined drug injection . . . method of Flaherty et al and Jenkins et al in the method of Mueller . . . since this is desirable to help maintain the channels, as taught by Flaherty et al, thus producing a method such as claimed" (Ans. 4). We are not persuaded.

Although Mueller discloses the formation of channels (FF 22-23), the Examiner has not adequately explained why one of ordinary skill in the art would have sealed an opening in one of these channels or delivered medicament through the sealed opening. In particular, the Examiner has not pointed to any teaching in Flaherty suggesting the desirability of maintaining revascularization channels by sealing their openings.

Conclusion

The Examiner erred in concluding that the applied references render claim 39 obvious. We therefore reverse the obviousness rejection of claim 39 and of claim 40, which depends from claim 39.

OBVIOUSNESS III

The Examiner rejects claim 41 as obvious over Flaherty in view of Jenkins, Mueller, and Jeevanandam (Ans. 4). The Examiner relies on Flaherty, Jenkins, and Mueller as discussed above (*id.*). The Examiner relies on Jeevanandam for teaching "the use of multiple vacuum ports to secure a channel-forming device to the cardiac wall so as to form chambers therein"

(*id.* at 4-5). The Examiner concludes that it would have been obvious "to provide multiple ports, as taught by Jeevanandam et al, since this provides secure fixation and to provide four ports, since the number of ports can be varied as desired, as taught by Jeevanandam et al, thus producing a method such as claimed" (*id.* at 5).

Appellant argues that the "arguments presented with regard to claims 39 and 40 . . . are equally applicable to claim 41" (App. Br. 19). Appellant also argues that Jeevanandam "does not teach multiple vacuum ports" (*id.*).

Issue

Did the Examiner err in concluding that the applied references render claim 41 obvious?

Findings of Fact

27. Jeevanandam discloses:

> a method for myocardial revascularization . . . , comprising entering the ventricle of the heart with a catheter having a lumen which houses a fiber which emits energy at a fiber end . . . and emitting energy from said fiber end in an amount sufficient to form a channel in the ventricular wall into the myocardium to thereby increase blood flow from the endocardium to the myocardium.

(Jeevanandam, col. 2, ll. 10-19.)

28. Jeevanandam also discloses that "the insertable end 24 of the [catheter 22] has gripping means extending therefrom in the form of three suctions cups 44" and that these "cups 44 provide a means to removably mount and stabilize the insertable end 24 to the inner ventricular wall, and

serves as a tripod for the end 24, and the fiber end 32" (*id.* at col. 4, l. 66, to col. 5, l. 4).

Analysis

Jeevanandam discloses a catheter with an insertable end having "gripping means extending therefrom in the form of three suctions cups 44 . . . to removably mount and stabilize the insertable end 24 to the inner ventricular wall" (FF 28). The Examiner does not show that Jeevanandam discloses a device having multiple vacuum ports. However, even assuming that it would have been obvious to connect a vacuum port to each of Jeevanandam's suction cups based on the disclosure in Mueller, the Examiner has not adequately explained how or why this disclosure is being combined with Flaherty and Jenkins to result in the method of claim 41.

Conclusion

The Examiner erred in concluding that the applied references render claim 41 obvious. We therefore reverse the obviousness rejection of claim 41.

SUMMARY

We affirm the obviousness rejection of claims 36-38. However, we reverse the written description rejection of claims 36-38, the obviousness rejection of claims 39-41, and the anticipation rejection of claims 42-44.

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED-IN-PART

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